FEB - 6 2014

k130864

510(k) SUMMARY

February 4, 2014

Office of Device Evaluation
U.S. Food & Drug Administration

In accordance with Section 807.92 (c), is hereby made the 510(k)-summary for our device **"c-max+ (plus)"P,** that we plan to introduce into interstate commerce for commercial distribution.

Applicant / 510(k)-owner: AAT Alber Antriebstechnik GmbH
Ehestetter Weg 11
D-72458 Albstadt-Ebingen
Phone: Tel. +49.7431.1295-0
Fax +49.7431.1295-35
Email: info@aat-online.de

Organization Number: 239600

Contact Person: Mrs. Stefanie D. Bankston
BEO MedConsulting Berlin GmbH
3001 Ferndale Dr.
League City TX 77573
Phone: 713-483 46 17
email: s.bankston@beoberlin.com

Devices Name:

a. Proprietary name: c-max+ (plus)
b. Common Name: Powered patient stairway chair lift
c. Classification Name: 21 CFR 890.5150 – Powered patient transport
d. Device Class: II
e. Classification Panel: Physical Medicine
f. Product Code: ILK

Identification of the legally marketed device to which we claim equivalence:

The **c-max+ (plus)** is substantial equivalent in intended use, design and function to the **c-max** by AAT Alber Antriebstechnik GmbH (K103122).

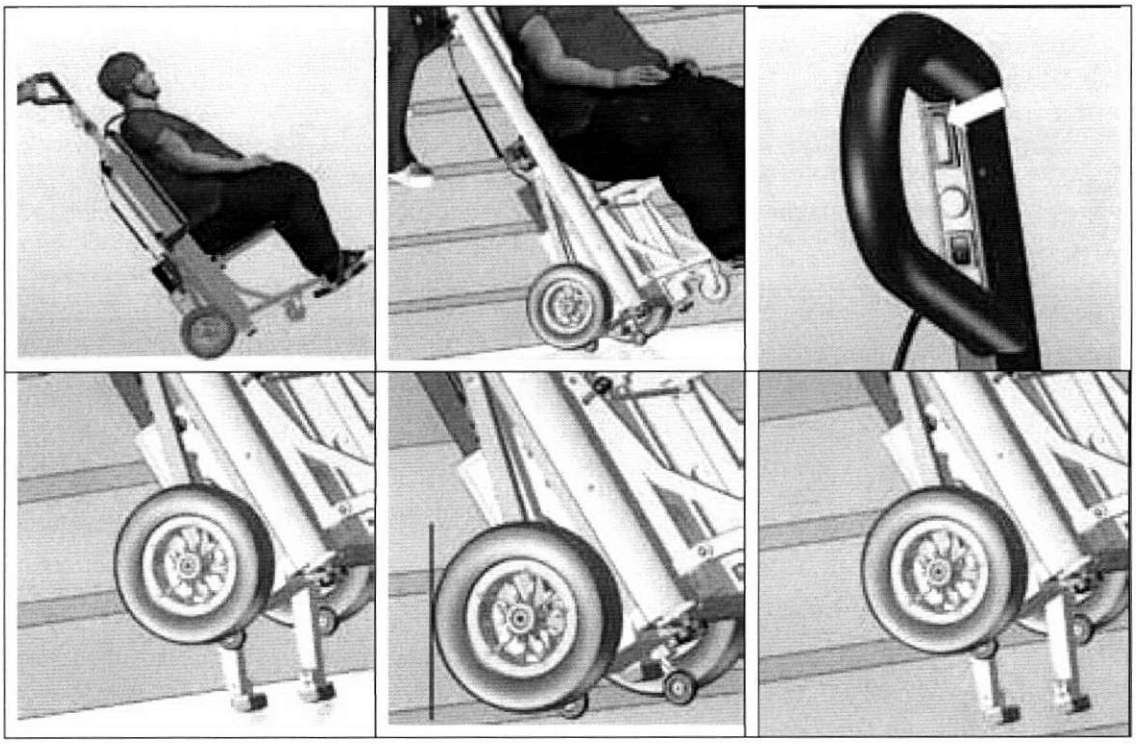
Device Description:

With the c-max+ people can transport a patient safely and comfortably up- and downstairs. The maximum load is 300kg. The device is safe due to automatic brakes and a rigid frame. It is suitable for almost all kinds of stairs, winding stairs excluded. The climbing system requires low maintenance and care.
On stairs as well as on level ground C-Max+ proves its versatility. Removable arm rests make easy transferring from one chair to another possible. Due to its compact dimensions and foldable foot rest, the C-Max+ is easy to manoeuvre even on very narrow stair cases. For small, compact apartments with narrow doorways, the C-Max+ represents the ideal solution

Scientific Concept: At the heart of the matter lies the patented climbing mechanism, which virtually climbs stairs all by itself. It also makes the C-Max+ particularly versatile and safe.

Function: Once the patient has seated and fastened the seat belt, the care attendant needs little physical power to handle the C-Max+. The C-Max+ is individually adjustable. Wheels make the transport on the floor easy. The battery-powered stair-climbing mechanism is user-controlled with adjustable speed and climbing-direction. The attendant can also choose a single-step-mode alternatively to fluent climbing. A safety-brake ensures safe stops during the stair-climbing.

C-Max+ ascends:



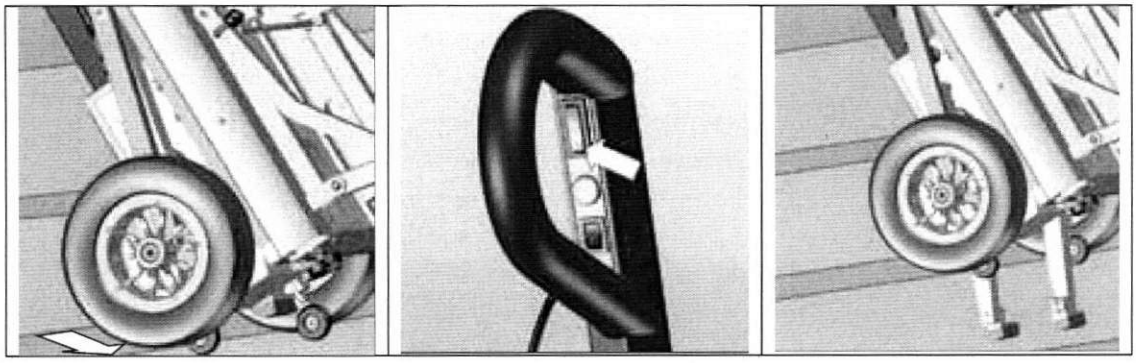
Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
Tel. +49.7431.1295-0 · Fax +49.7431.1295-35 · info@aat-online.de · www.aat-online.de
Postfach 100 560 · D-72426 Albstadt-Ebingen

Amtsgericht Stuttgart HRB 1006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Thomas Alber, Markus Alber

Unsere Bankverbindungen
Sparkasse Zollernalb · Konto 31712831 · BLZ 65351260
Swift Code: SOLADES1BAL
IBAN: DE06 6535 1260 0031 7128 31

Volksbank Ebingen eG · Konto 83153004 · 65390120
LBBW · Konto 4765671 · 60050101

C-Max+ descends:



Features of the device

1. Handle (adjustable)
2. UP/DOWN switch
3. Speed control
4. ON/OFF switch
5. Quick pin
6. Port for magnetic charger system
7. Helix cable
8. Seat belt system with lap-sash sea
9. Locking pin foot rest
10. Seat unit
11. Release lever
12. Foot belt with two point belt
13. Foot rest (foldable)
14. Guiding handles
15. Main wheel
16. Climber and climbing foot
17. Safety brake
18. Climbing unit
19. Step counter with LED
20. Battery pack
21. Tightening knob
22. Single step switch
23. LED
24. Locking screw
25. Locking pin handle adjustment

Intended use:

Powered patient stairway chair lift; Intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
Tel. +49.7431.1295-0 · Fax +49.7431.1295-35 · info@aat-online.de · www.aat-online.de
Postfach 100 560 · D-72426 Albstadt-Ebingen

Amtsgericht Stuttgart HRB 1006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Thomas Alber, Markus Alber

Unsere Bankverbindungen
Sparkasse Zollernalb · Konto 31712831 · BLZ 65351260
Swift Code: SOLADES1BAL
IBAN: DE06 6535 1260 0031 7128 31

Volksbank Ebingen eG · Konto 83153004 · 65390120
LBBW · Konto 4765671 · 60050101

Indication for use:

Support for disabled seated persons i.e. with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc. to move from one level to another.

Performance Standards:

Non-clinical tests were performed to determine substantial equivalence. The tests were performed according to recognized standards for powered patient stairway chair lifts. These are the applicable standards:

- To demonstrate the device's general safety, we performed non-clinical tests according to EN 12182: Technical aids for disabled persons-general requirements and test methods.
- To demonstrate the device's safe function under different standardized climatic conditions, we performed non-clinical tests according to ISO 7176-9: Wheelchairs - Part 9: Climatic tests for electric wheelchairs.
- To demonstrate the device's electrical safety, we performed non-clinical tests according to ISO 7176-14: Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters -Requirements and test methods
- To demonstrate the device's safety concerning flammability, we performed non-clinical tests according to ISO 7176-16: Wheelchairs - Part 16: Resistance to ignition of upholstered parts -- Requirements and test methods
- To demonstrate the device's electromagnetic-compatibility, we performed non-clinical tests according to ISO 7176-21: Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- To demonstrate the device's mechanical and functional safety, we performed non-clinical tests according to ISO 7176-23: Wheelchairs - Part 23: Requirements and test methods for attendant-operated stair-climbing devices
- To demonstrate the device's biocompatibility, we performed non-clinical tests according to ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
Tel. +49.7431.1295-0 · Fax +49.7431.1295-35 · info@aat-online.de · www.aat-online.de
Postfach 100 560 · D-72425 Albstadt-Ebingen

Amtsgericht Stuttgart HRB 1006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Thomas Alber, Markus Alber

Unsere Bankverbindungen
Sparkasse Zollernalb · Konto 31712831 · BLZ 65351260
Swift Code: SOLADES1BAL
IBAN: DE06 6535 1260 0031 7128 31

Volksbank Ebingen eG · Konto 83153004 · 65390120
LBBW · Konto 4765671 · 60050101

Comparison to legally marketed device (Substantial Equivalence):

The c-max+ (plus) is essentially equivalent in intended use, design and function to the c-max by AAT Alber Antriebstechnik GmbH (K103122).

The Chart below summarizes the similarities and differences:

	c-max+ (plus)	***c-max (K103122) Predicate device***
Indication for use	Same but the use on winding stairs is excluded	*support for disabled seated persons e.g. with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc. to move from one level to another.*
Manual wheelchair accommodation	same	*Integrated seating-unit. No wheelchair adaption*
Accessories / Options	Head rest, seat belts, different footrests; power charger for the car, magnetic charging system	*Head rest, seat belts, different footrests; power charger for the car*
Stairway Configuration	Straight and U-turn curves. Up to **8**" max. step-height. Stairs must be in good condition. Interior/exterior. Most stairway material types	*Curves, spiral turns. Up to **9**" max. step-height. Stairs must be in good condition. Interior/exterior. Most stairway material types*
Level of operator difficulty	same	*Requires some coordination. Depends on rider weight, number of stairs and operator ability. Automatic braking.*
Portability for Travel	Breaks down into 3 parts, heaviest part is 110 lbs. Statement: due to its ability to carry a higher load the frame design is more rigid.	*Breaks down into 4 parts, heaviest part is 37 lbs.*
Performance		
Max. Load	300 kg	*140 / 160 kg*
steps	Approx. 300	*Approx. 375*
speed	3-8 steps / minute continually adjustable Statement: due to its ability to carry a higher load, it is slower than the p.d.	*8 – 23 steps / minute continually adjustable*
Frame/chassis	Reinforced rigid metal profile	*Rigid metal profile*
Technical data		
Height	1490 - 1775 mm	*1090 - 1400 mm*
Width	527 mm	*440 - 485 mm*
Total weight	79.3 kg	*33,4 kg*
Power supply		
battery	same	*2x12V, 275 W*

Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
Tel. +49.7431.1295-0 · Fax +49.7431.1295-35 · info@aat-online.de · www.aat-online.de
Postfach 100 560 · D-72426 Albstadt-Ebingen

Amtsgericht Stuttgart HRB 1006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Thomas Alber, Markus Alber

Unsere Bankverbindungen
Sparkasse Zollernalb · Konto 31712831 · BLZ 65351260
Swift Code: SOLADES1BAL
IBAN: DE06 6535 1260 0031 7128 31

Volksbank Ebingen eG · Konto 83153004 · 65390120
LBBW · Konto 4765671 · 60050101

		rechargeable
battery charger	same	*(input) 90-240 V AC (output)24 V DC*
motor	same	*24V / 275 W / DC*

Analysis on the differences:

- The main difference between the subject device C-Max+ und the predicate device C-Max is its max. load. The C-Max+ can carry twice as much as the predicate device. Due to this higher performance, the C-max+ (plus) has a reinforced structure that makes him stronger and slightly heavier and slower.
- Due to its ability to carry a higher load, it is slower than the predicate device. The speed difference doesn't cause any safety problems.
- The fact that the c-max+ total weight is way higher than the c-max's one is only due to the possibility of being able to carry a higher max. load. The frame is more rigid. The weight difference doesn't cause any safety problems.

Quality Assurance and Manufacturing Controls:

AAT Alber Antriebstechnik GmbH operates to an established and certified quality management system according to ISO 9001, and ISO 13485.

Conclusion:

The subject device C-Max+ is as safe, as effective, and performs as well as the predicate device but with a higher max. load. The performed non-clinical tests demonstrate the safety of the subject device's performance, electricity, electromagnetic-compatibility, mechanical strength and durability, flammability and biological/toxicological aspects.

Sincerely,

AAT Alber Antriebstechnik GmbH

Michael Vent
p.p. Stefanie D. Bankston
Official Correspondent for AAT Alber Antriebstechnik GmbH

SD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

AAT Alber Antriebstechnik GmbH
c/o Stefanie D. Bankston
BEO MedConsulting Berlin GmbH
Texas Office
3001 Ferndale Dr.
League City, TX 77573

Re: K130864
Trade/Device Name: c-max+ (plus)
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: Class II
Product Code: ILK
Dated: December 3, 2013
Received: December 27, 2013

Dear Ms. Bankston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130864

Device Name
c-max+ (plus)

Indications for Use *(Describe)*
The product c-max+ (plus) offers motorized stair-climbing support for disabled seated persons e.g. with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc. to move from one level to another.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."